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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
GEISEL, KARA E

ART UNIT	PAPER NUMBER
2877	#9

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/680,436	MELLER, PAUL
	Examiner	Art Unit
	Kara E Geisel	2877

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☒ Claim(s) *11-13,25 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6, 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in this application.

Information Disclosure Statements

The information disclosure statements filed on October 6th, 2000 and October 26th, 2001 have been fully considered by the examiner.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because it does not disclose the applicant's improvements over prior art, and does not disclose the organization and operation of the apparatus. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 11-13, 25, and 33 are objected to because of the following informalities: minor grammatical errors.

In regards to claims 11 and 13, lines 3 and 4, respectively, applicant discloses, "said a second". This should be changed to --said second--.

In regards to claim 12, line 3, "proportion" should be changed to --portion--.

In regards to claim 25, lines 2-3, "in of claim 1" should be changed to --in claim 1--.

In regards to claim 33, line 4, "frorn" should be changed to --from--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 10-13, 16, 18, 20, 23, 26, 28-30, and 35 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph. The structure, which goes to make up the device, must be clearly and positively specified in these claims. The structure must be organized and correlated in such a manner as to present a complete operative device.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 19, line 3, it is unclear which diaphragm applicant is referring to. Clarification is required.

Claims, which are dependent from claim 1, 10-13, 16, 18, 19, 20, 23, 26, 28-30, and 35 inherit the problems of this claim, and are therefore also rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 22-23, 25, 29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815).

In regards to claim 1, Bradwell discloses an apparatus for carrying out optical measurements (column 1, lines 60-63), which comprises a light source having a spectral range (fig. 5, 110), a light filter on the common beam axis for separation of a desired spectral region (fig. 5, 111 and column 3, lines 36-39), a diaphragm on the common beam axis for shaping the beam (fig. 5, 112), and a sensor for detecting a signal generated by a material to be measured (fig. 5, 114). In another embodiment, the apparatus includes a sensor for detecting a reference signal (fig. 7, 353 and column 5, lines 23-26). Although the patent does not explicitly disclose that there is a light guidance arrangement for guiding the light along a common beam axis from the light source to a reaction location (fig. 5, 113), it would be obvious to one of ordinary skill in the art to place a light guidance arrangement into the device in order to have more degrees of freedom of where to place the light source.

In regards to claim 2, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the light source of the combined system emits light having a spectral region in the UV-visible region (Bradwell column 2, lines 7-11).

In regards to claim 3, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the light source is a xenon pulsed light source (column 3, lines 1-4).

In regards to claim 5, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the light source is a light emitting diode (column 3, lines 11-15).

In regards to claim 22, the optical measurement apparatus of claim 1 is discussed above. Furthermore, amplifier and conversion means for further measurement processing (fig. 7, 329 and 354-356; column 5, lines 23-36) are operably configured with the sensor (fig. 7, 314).

In regards to claim 23, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the apparatus comprises a processor unit (fig. 7, 356) for common control of the components, evaluation and presentation of the signal (column 5, 32-36).

In regards to claim 25, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the apparatus is used in a process for in-vitro diagnosis in a nephelometric analyzer (column 1, lines 51-54).

In regards to claim 29, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the system has a second filter (fig. 4, 20) for separating the desired spectral region (column 3, lines 34-39).

In regards to claim 37, the optical measurement apparatus of claim 1 is discussed above. Furthermore, the filter (fig. 5, 111) is used for separating out and suppressing light of an undesirable spectral range (column 3, lines 34-39).

In regards to claim 38, the optical measurement apparatus of claim 1 wherein the light source has a spectral region in the UV-visible range is discussed above. Furthermore, the apparatus is used in a process for in-vitro diagnosis in a nephelometric analyzer (column 1, lines 51-54).

Claims 4, 6, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Hafeman et al. (USPN 5,959,738).

In regards to claims 4 and 31-32, the optical measurement apparatus of claim 1 is discussed above. The light source is either a Xenon flash lamp or a light emitting diode, but Bradwell does not explicitly disclose the full spectral region of the light source.

Hafeman discloses an optical measuring apparatus that can be used in a nephelometric device (column 30, lines 42-58) such as the device described by Bradwell. Hafeman discloses that the device uses a Xenon flash lamp, which has a spectral region of 200-1100 nm (column 27, lines 20-29), which is the region from UV to near infrared. Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to substitute this xenon flash lamp, having a spectral region that ranges from UV to near infrared, as Bradwell's Xenon flash lamp, in order to have a full spectral region to choose from.

In regards to claim 6, the optical measurement apparatus of claim 1 wherein the light source is a light emitting diode (LED) is discussed above. Bradwell does not explicitly disclose the full spectral region of the LED.

Hafeman discloses an optical measuring apparatus that can be used in a nephelometric device (column 30, lines 42-58) such as the device described by Bradwell. Hafeman discloses that the device has a spectral region of 750 to 2500 for the measurement in the near infrared, and that light emitting diodes are used in this spectral range for their distinct quality of having a high light intensity at narrow bandwidths (column 7-8, lines 63-67 and 1-16). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to have included an LED with a range of 800 to 950 in Bradwell's device in order to measure scattering in the near infrared spectral region.

Claims 7, 21, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Harju (USPN 6,042,785).

In regards to claims 7 and 26, the optical measurement apparatus of claim 1 is discussed above. Bradwell does not explicitly disclose that the light source is used in pulsed operation.

Harju discloses a device that can be used to take nephelometric measurements (column 11, lines 59-65). His device includes a continuous light source and a pulsed light source and pulsing means, wherein the pulsed light source is included to enlarge the diversity of usage of the device (column 2, lines 36-49) and to obtain time resolved excitation readings of the sample (column 3, lines 18-20). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to add a pulsed light source and it's pulsing means in Bradwell's optical measurement apparatus in order to increase the diversity of usage of the device and to obtain time resolved excitation of the sample.

In regards to claim 21, the optical measurement apparatus of claim 1 with an added pulsed light source is discussed above. Furthermore, the combined system includes an optoelectronic component in order to control the pulses of the light source (Harju, column 3, lines 21-23).

In regards to claim 28, the optical measurement apparatus of claim 1 combined with a second light source is discussed above. Furthermore, the combined system has two light guidance arrangements (Bradwell fig. 5, 111 and 112; Harju, fig. 2, 92-94) in order to direct the light beams toward the sample.

Claims 1, 8 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (USPN 4,692,883).

In regards to claims 1 and 8, Nelson discloses an optical measurement apparatus comprising a light source (fig. 1, 11), a light guidance arrangement (fig. 1, 13, 19, 20), two filters for separation of a spectral region (fig. 1, 15, 23), two diaphragms (fig. 1, 25, 26) for shaping the beam (column 3, lines 41-43), a reaction location (fig. 1 27), a reference source (fig. 1, 17) for creating a reference signal, and a sensor for detecting both the reference and the source signal (fig. 1, 45). Although the filter and the diaphragm are not on the common beam axis as the sample, this is a design consideration, and therefore, it would have been obvious to one of ordinary skill in the art to place the filter and the diaphragm on the common beam axis as the sample. Furthermore, the light guidance arrangement is constructed from discrete individual components (fig. 1, 13, 20, 19, 21, 22) on a fixed connection axis.

In regards to claim 35, Nelson's optical apparatus of claim 1 is discussed above. The apparatus further comprises directing the signal to an entrance slit (fig. 1, 33) of a spectrophotometer unit (fig. 1, 33, 35, 37, 43, and 45).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Winslow et al. (USPN 5,400,137) as cited by applicant.

In regards to claim 9, the optical measurement apparatus of claim 1 is discussed above. The apparatus does not have a flexible optical fiber in the light guidance arrangement.

Winslow discloses a device for optical measuring. Winslow's device has a flexible optical fiber in a light guidance arrangement (fig. 2, 68). This optical fiber is used to combine two light sources so that fluorescence and turbidity measurements can be taken simultaneously (column 3, lines 15-24). Therefore, it

would have been obvious to one of ordinary skill at the time the invention was made to add a flexible optical fiber into the light guidance arrangement of Bradwell's device, in order to combine the light of the light source with another light source so that simultaneous measurements could be taken.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Cook et al. (USPN 6,175,750).

In regards to claim 10, the optical measurement apparatus of claim 1 is discussed above. The apparatus does not have an insert for accommodating a filter for calibration of the light source.

Cook discloses a method for calibrating an optical device. The method places an optical filter between the light source and the object being analyzed (column 1, lines 50-55). This method of calibration is done in a non-invasive manner, so that the object being imaged does not suffer any damage (column 2, lines 15-19). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to have an insert for a calibration filter in Bradwell's device, where the calibration filter could be placed on the common beam axis so that calibration of the optical measuring device could be done without damaging a sample being tested.

Claims 11, 13-17, 19-20, 30, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Meller (EP 0 997 726) as cited by applicant.

In regards to claims 11 and 30, the optical measurement apparatus of claim 1 is discussed above. Bradwell does not disclose the use of a second diaphragm.

Meller discloses an optical measurement apparatus. Meller's device includes a second diaphragm and more detection devices after the light hits the sample (fig. 2, 15) for further discriminating the light range coming out of the sample. This is done so that the device can be more versatile and can be used for multiple functions, such as a nephelometer, and a spectrophotometer. Therefore it would have been obvious to one of ordinary skill at the time the invention was made to include a second diaphragm and it's accompanying

detection devices to further limit the light range to be measured in order make this device more versatile so this device could be used as both a nephelometer and a spectrophotometer.

In regards to claim 13, the optical measurement apparatus of claim 1 with a second diaphragm is discussed above. Furthermore, the second diaphragm masks out light impinging at small angles around said common beam axis, wherein said second diaphragm intersects said common beam axis (fig. 2, 15).

In regards to claims 14 and 33, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles around the common beam axis is discussed above. Furthermore, the diaphragm is also capable of transmitting light impinging at small angles around 0° from the material (Meller fig, 2, 13) to be measured and relative to said common beam axis for further measurement (fig. 2, 16).

In regards to claims 15 and 34, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles and transmitting light at angles around 0° from the common beam axis is discussed above. Furthermore, the light is detected at angles of less than 5° around the forward direction of said common beam axis (fig. 2, 16).

In regards to claim 16, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles and transmitting light at angles around 0° and less than 5° from the common beam axis is discussed above. Furthermore, the impinging light is guided out from said common beam axis with a beam deflection arrangement (fig. 2, 16).

In regards to claim 17, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles and transmitting light at angles around 0° and less than 5° from the common beam axis and also comprising a beam deflection arrangement is discussed above. Furthermore, the beam deflection arrangement (fig. 2, 16) is connected to a feedback and detection system. In order to arrange this connection it would be obvious to one of ordinary skill in the art at the time the invention was made to use an optical waveguide with corresponding connection components.

In regard to claims 19 and 36, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles and transmitting light at angles around 0° from the common beam axis is discussed above. Furthermore, the scattered light of the combined system of said one signal passing through the second diaphragm is imaged onto an input of a detector (fig. 2, 9), by a lens system (fig. 2).

In regards to claim 20, the optical measurement apparatus of claim 1 with a second diaphragm that is capable of masking out light of small angles and transmitting light at angles around 0° from the common beam axis, wherein the light is imaged onto an input of a detector is discussed above. Furthermore, the combined system has a second filter (Bradwell, fig. 4, 20) for separating the desired spectral region (column 3, lines 34-43).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of McCluney (USPN 6,042,785) as cited by applicant.

In regards to claim 12, the optical measurement apparatus of claim 1 is discussed above. The device does not have a beam splitter for guiding a portion of the light as a reference signal.

McCluney discloses an optical measurement apparatus. McCluney's device includes a beam splitter (fig. 1, 21) for splitting some of the light from the laser to a monitoring detector and sending the rest of the light through the sample. This is done so that the laser can be monitored (column 3, lines 2-9). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to use a beam splitter in Bradwell's device, to guide a portion of the light as a reference signal to a detection device, in order to monitor the light source.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Modell et al. (USPN 6,104,945).

In regards to claim 24, the optical measurement apparatus of claim 1 is discussed above. The device does not have a dichroic filter, which combines the light from said one light source onto a common beam guidance arrangement.

Modell discloses an apparatus for determining optical characteristics of a material to be tested (column 1, lines 9-20). His device includes a dichroic filter (fig. 2, 25), which is used to guide the light of a light source onto the same axis as a sample (column 9 lines 45-55). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to use a dichroic filter in Bradwell's device as a means for combining an exciting light source onto a common beam guidance arrangement to guide the light towards a sample.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) in view of Harju (USPN 6,042,785) as applied to claim 26 above, and further in view of Hafeman et al. (USPN 5,959,738).

In regards to claim 27, the optical measurement apparatus of claim 1 combined with a second light source is discussed above. The combined system does not disclose the two light sources having different spectral regions.

Hafeman discloses an optical measuring device. Hafeman's device can have multiple light sources, each having different spectral regions (column 8, lines 1-5). This is done so that selected light sources can be turned on to get the desired range of light needed for testing (column 8, lines 6-16). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made, to have two different light sources with two different spectral regions, so that a specific range of light needed for detection could be obtained.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (USPN 4,889,815) as applied in claims 1-3, 5, 22-23, 25, 29, and 37-38 above, and further in view of Tayi (USPN 6,096,561).

In regards to claim 39, the optical measurement apparatus of claim 1 is discussed above. Bradwell does not disclose that the reference signal and the scattered light source signal are measured simultaneously.

Tayi discloses an optical measurement device used for multiple types of measurements, including nephelometric (columns 10-11, 66-67 and 1-15, respectively). The sensor of the system, shown in fig. 19, detects both a reference signal and the source signal simultaneously. This is done so the system can quickly multiply the two together to get amplitude information on the source signal (column 39, lines 16-39). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made, to replace the two sensors of Bradwell's apparatus (fig. 7, 312 and 314), with a sensor that can simultaneously measure one reference signal and one signal generated by the material, in order to obtain amplitude information on the material signal.

In regards to claim 40, combining the optical measurement apparatus of claim 1 with a sensor that simultaneously measures a reference signal and a source signal is discussed above. Furthermore, the apparatus is used in a process for in-vitro diagnosis in a nephelometric analyzer (Bradwell column 1, lines 51-54).

Allowable Subject Matter

Claim 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

As to claim 8, the prior art of record, taken alone or in combination, fails to disclose or render obvious that the detected light of at least one signal is directed to an entrance slit of a spectrophotometer unit.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is 703 305 7182. The examiner can normally be reached on Monday through Thursday, 8am to 5pm and every other Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font can be reached on 703 308 4881. The fax phone numbers for the organization where this application or

proceeding is assigned are 703 872 9318 for regular communications and 703 872 9319 for After Final communications. For inquiries of a general nature, the Customer Service fax number is 703 872 9317.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1782.

F.L. Evans
Primary Examiner
Art Unit 2877

K.G

KEG
November 1, 2002